THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOSEPH C. COLACICCO, INDIVIDUALLY AND AS EXECUTOR OF THE ESTATE OF LOIS ANN COLACICCO, DECEASED,	:	
Plaintiffs,	:	
vs.	:	**CIVIL ACTION NO.:** **JURY TRIAL DEMANDED**
APOTEX, INC., AND APOTEX CORP., AS A SUBSIDIARY OF APOTEX, INC., AND SMITHKLINE BEECHAM, d/b/a GLAXOSMITHKLINE,	:	
Defendants.	:	

COMPLAINT

Plaintiff, Joseph C. Colacicco, residing at 445 West Broadway, Long Beach, New York, 11561, by his attorneys, CUNEO, POGUST & MASON, LLP, as and for the Verified Complaint herein allege upon information and belief the following:

NATURE OF ACTION

1. Plaintiff, Joseph C. Colacicco, individually and as the Executor of the Estate of Lois Ann Colacicco ("Lois"), by his undersigned counsel, brings this wrongful death and survival action against Defendants Apotex Inc., Apotex Corp., and SmithKline Beecham, Inc. ("SKB"), d/b/a GlaxoSmithKline ("GSK"), for breach of express and implied warranty, fraud, negligent misrepresentation, intentional infliction of emotional distress, negligent infliction of emotional distress, negligence, negligence *per se*, strict

products liability, violation of consumer protection laws, and punitive damages. Plaintiff alleges upon personal knowledge and belief as follows:

2. Plaintiff's decedent, 55-year-old Lois Ann Colacicco, committed suicide on October 28, 2003, as a direct and proximate result of her ingestion, from on or about October 6 to October 28, 2003, of a generic pharmaceutical drug known as "paroxetine hydrochloride."

3. Generic paroxetine hydrochloride is studied, tested, designed, developed, manufactured, mixed, inspected, produced, labeled, advertised, marketed, promoted, distributed, and sold by Apotex, Inc. and Apotex Corp.

4. At all times relevant to this action, generic paroxetine hydrochloride was approved for labeling, advertising, marketing, promotion, distribution, and sale by the United States Food and Drug Administration ("FDA") as a "bioequivalent" of the brand-name pharmaceutical drug, Paxil®, which, at all times relevant to this action, was studied, tested, designed, developed, manufactured, mixed, inspected, produced, labeled, advertised, marketed, promoted, distributed, and sold by Defendant GSK.

5. This is a wrongful death and survival action to recover damages suffered as the direct and proximate result of Defendants' acts and/or omissions in studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertising, marketing, promoting, distributing, and/or selling Paxil® and/or generic paroxetine hydrochloride.

PARTIES

6. At all times relevant herein, Plaintiff and his decedent were residents of the State of New York, and Plaintiff currently is a resident of the State of New York.

7. Apotex, Inc. is a Canadian corporation with its principle office and place of business located at 150 Signet Drive, Weston, Ontario, M9L 1T9, Canada.

8. Apotex Corp., is a Florida Corporation with its principle office and place of business at 2400 North Commerce Parkway, Suite 400 Weston, Florida, 33326.

9. It is submitted, upon information and belief, that Defendants Apotex, Inc. and Apotex Corp. were, at all times relevant to this action, responsible for studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertisement, marketing, promoting, distributing and selling generic paroxetine hydrochloride throughout the United States and in the Commonwealth of Pennsylvania.

10. Upon information and belief, on or about December 2000, the two companies of Glaxo Wellcome and Defendant SmithKline Beecham, Inc. ("SKB"), merged with each other to become GlaxoSmithKline, Inc., *i.e.*, Defendant GSK.

11. Upon information and belief, Defendant GSK is a successor in interest to Defendant SKB.

12. Upon information and belief, on or about December 2000, Defendant GSK assumed the assets and liabilities of Defendant SKB.

13. Defendant GSK is a Pennsylvania Corporation with its principle office and place of business at One Franklin Plaza, Philadelphia, Pennsylvania, 19102, and, at all times relevant hereto, studied, tested, designed, developed, manufactured, mixed, inspected, produced, labeled, advertised, marketed, promoted, distributed, and sold Paxil® throughout the United States and the world and does substantial and continuing business in the Commonwealth of Pennsylvania, which business included that giving rise to the claims in this case.

14. As a result of its studies, testing, design, development, manufacture, mixing, inspection, production, labeling, advertisement, marketing, promotion, distribution, and/or sale of Paxil®, either directly or indirectly through third parties or related entities, Defendant GSK obtained the benefits of the laws of the Commonwealth of Pennsylvania and profited from Pennsylvania commerce.

JURISDICTION AND VENUE

15. Jurisdiction is premised upon diversity of citizenship, pursuant to 28 U.S.C. §1332, in that: Plaintiff is a citizen of the State of New York and Plaintiff's decedent was a citizen of the State of New York at the time of her death; Defendants Apotex, Inc. and Apotex Corp. (hereinafter, collectively "Defendant Apotex"), are, respectively, a corporation incorporated under the laws of Canada, with its principal place of business in Canada, and a corporation incorporated under the laws of the State of Florida, with its principal place of business in the State of Florida; Defendant GSK is a corporation incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business in the Commonwealth of Pennsylvania; and the amount in controversy exceeds, exclusive of interest and costs, Seventy-five Thousand Dollars ($75,000.00).

16. Venue is proper in this judicial district because: (1) a substantial part of the events or omissions giving rise to Plaintiff's claims, including but not limited to Defendant GSK's fraud and concealment, occurred within Pennsylvania and/or were intended to occur in or have consequences in Pennsylvania; see 28 U.S.C § 1391(a)(2); and (2) Defendant GSK is a corporation subject to personal jurisdiction in this judicial district. See 28 U.S.C. § 1391(c).

FACTUAL ALLEGATIONS

A. Serotonin and Suicide

17. Serotonin, which is commonly identified in scientific literature as "5HT," is an important and naturally occurring chemical which is found in the brain and throughout other parts of the body. It is one of a number of chemicals in the brain known as "neurotransmitters." It is widely believed in the scientific community that serotonin is somehow related to mood, but also, that it affects inhibition, self-control, impulse and aggressiveness.

18. Some years ago, several studies were conducted which compared, following autopsy, the brains of people who had committed suicide to the brains of people who had died by other causes. These studies demonstrated that those people who had committed suicide had lower levels of serotonin, 5HT, in the synaptic clefts of their brains than people who had died of other causes. Based on that observation, it was hypothesized that a drug that could control the serotonergic levels in the synaptic clefts of the brain might enhance mood and reduce depression.

19. This hypothesis led to the development of an entire class of drugs called "selective serotonin reuptake inhibitors" ("SSRIs"), which have been heavily advertised and commercialized, with great success in the United States and abroad, as highly selective medicines capable of treating a host of maladies simply by regulating the level of serotonin in the brain.

20. It is not scientifically or medically possible to assay, or measure, the levels of serotonin in the brain in a person who is alive, but rather, such assay can only be done following death. Furthermore, it is not known precisely why or how SSRIs elevate or

alter the mood of some individuals; nor is there a consensus in the scientific or medical community as to what constitutes a "proper" chemical balance of serotonin in the brain.

21. Dr. J. John Mann coauthored an article entitled "The emergence of suicidal ideation and behavior during antidepressant pharmacotherapy," which was published in the November 1991 volume of the Archives of General Psychiatry. In that article, Dr. Mann, who was later retained as an expert by Defendant GSK, discusses the phenomenon of "iatragenic suicide" – *i.e.*, physician-induced suicide – and postulates that there may be a "small vulnerable subpopulation" of patients for whom SSRIs pose a risk of suicide or aggression. Also discussed in the article, and in other later publications, were Dr. Mann's suggested protocols for four studies that could be used by SSRI manufacturers to test the hypothesis that SSRIs pose a risk of suicide and violence for a "small vulnerable subpopulation" of patients.

22. Neither Defendant GSK nor Defendant Apotex ever followed Dr. Mann's suggested study protocols. However, sometime after Dr. Mann's article, researchers at Eli Lilly & Company, the manufacturer of Prozac, which was one of the very first SSRIs, drafted what they labeled a "rechallenge protocol" in order to test Dr. Mann's hypotheses. That protocol followed one of the four test designs suggested by Mann's article.

23. At the time when that test was conducted, Dr. David Wheadon was an employee of Eli Lilly & Company and listed as a clinical investigator for the study. Dr. Wheadon is presently the Senior Vice President for U.S. Regulatory Affairs at Defendant GSK.

24. In March 1995, Dr. David Dunner of the University of Washington's Department of Psychiatry was listed as a co-author of an article entitled, "Reduction of suicidal thoughts with paroxetine in comparison with reference antidepressants and placebo," which appeared in the March 1995 issue of the journal of European Neuropsychopharmacology. The article, which was sponsored in part by Defendant SKB, represented that Dunner had analyzed the data of clinical studies involving Paxil® and concluded that Paxil® is less likely to lead to suicidal thoughts than both the older antidepressant, Imipramine, and placebo. Dunner later admitted to the media that he was a "ghostwriter" for that article and that he had never reviewed any of the clinical trial data discussed in the article and, in fact, had not participated at all in the authoring of the article.

25. In the last decade, including dates prior to October of 2003, there has been a host of peer-reviewed scientific literature linking SSRIs to violence – both self-directed and other-directed. Such literature discusses, *inter alia*, findings in the early 1990s from world-class experts, including Drs. Martin Teicher and Jonathan Cole, and Nurse Carol Glod, as well as Dr. David Healy and his colleagues in the United Kingdom, warning about the rise in violence and suicide associated with the use of SSRIs.

B. Defendant GSK's Conduct

26. Paxil® is a powerful psychoactive medication, which is included in the SSRI class of drugs and which operate by altering a person's serotonergic functioning.

27. It is submitted that, prior to October of 2003, Defendant GSK had acknowledged, internally but not publicly, that: (1) the single best predictor of aggression

is a prior history of aggression; and (2) aggressive behavior by patients with no history of suicide attempts is related to altered serotonergic function.

28. Prior to October of 2003, Defendant GSK, in the course of conducting business in Pennsylvania, was aware that: (1) Paxil® and other SSRIs are not efficacious for some adults taking the drug for depression and/or anxiety; and (2) some adults taking Paxil® and other SSRIs are at increased risk of experiencing suicidal ideation and engaging in self-directed violence or suicidal behavior.

29. At no time prior to October of 2003, did Defendant GSK inform the general public, the FDA, Defendant Apotex, Plaintiff's decedent's treating and/or prescribing physicians, and/or Plaintiff's decedent that: (1) Paxil® and other SSRIs were not efficacious for some adults taking the drug for depression and/or anxiety; or (2) some adults taking Paxil® and other SSRIs were at an increased risk of experiencing suicidal ideation and engaging in self-directed violence or suicidal behavior.

30. Prior to October 2003, Defendant GSK, in the course of conducting business in Pennsylvania, withheld said information from the public at large, various governmental agencies, including the FDA, Defendant Apotex, Plaintiff's decedent's treating and/or prescribing physicians, and/or Plaintiff's decedent, notwithstanding that Defendant GSK knew that physicians were prescribing Paxil® to adults throughout the world.

31. Prior to October 2003, Defendant GSK, in the course of conducting business in Pennsylvania, engaged in a concerted effort to withhold negative information concerning Paxil® and misrepresented data concerning Paxil®'s safety and efficacy when prescribed for depression in adults. Defendant GSK suppressed the negative results

of the various studies, which failed to demonstrate Paxil®'s effectiveness and indicated an increased risk of suicidal thinking and acts.

32. Prior to October of 2003, Defendant GSK, in the course of conducting business in Pennsylvania, misrepresented the results of its research on Paxil® as a treatment for adults to its sales representatives who promote Paxil® to physicians. The company portrayed the drug as having remarkable efficacy and safety in the treatment of, *inter alia*, depression.

33. Prior to October 2003, Defendant GSK was privy to reasonable evidence that antidepressant drugs that regulate serotonin, such as Paxil®, cause "akathisia," which is a syndrome characterized by intense inner-restlessness often manifesting itself in constant physical movement, which in turn can lead to suicide.

34. Notwithstanding the aforesaid, prior to October 2003, Defendant GSK insisted that, unless and until someone proved a causal relationship between SSRIs, including Paxil®, and suicide, it would not warn physicians or the public about the risks of suicide posed by SSRIs, including Paxil®.

35. In June 2003, the FDA's British counterpart, the Medicines and Healthcare Products Regulatory Agency ("MHRA") recommended a ban on Paxil® for children under the age of 18 in the United Kingdom due to increased risk of suicide.

36. In early 2004, FDA drug-safety analyst Andrew Mosholder was assigned to review Defendant GSK's Paxil® trials and noticed that a number of events that looked like suicide attempts had been subsumed under the term "emotional lability." After conducting his own analysis on Paxil®, Mosholder concluded that "children on them

[SSRIs] were almost twice as likely to experience suicidal thoughts or exhibit suicidal behavior as those taking placebos."

37. Although Mosholder's study and the MHRA's ban focused on children, the conclusion that "antidepressant drug treatment is associated with an increase in suicidal adverse events compared to placebo" cannot be overlooked with respect to adults.

38. In March of 2004, the FDA asked that several antidepressants be accompanied by a label noting that all patients should be watched closely for signs of increased depression or suicidal leanings.

39. In June 2004, New York State Attorney General Eliot Spitzer filed suit against Defendant GSK under New York law, charging the drug manufacturer with suppressing evidence of Paxil®'s harm to children and adults and misleading physicians. The New York complaint asserted as well that Defendant GSK "has repeatedly misrepresented the safety and efficacy outcomes from its studies of paroxetine [Paxil®] as a treatment for MDD [Major Depressive Disorder] in a pediatric population to its employees who promote paroxetine to physicians."

40. In August 2004, Defendant GSK settled with the New York Attorney General for $2.5 million, plus a commitment to maintain the policy of posting clinical trial results, for all drugs marketed by the company.

41. On October 15, 2004, the FDA set forth that all antidepressants, including Paxil®, *must* carry the government's "black box" safety alert to warn that the drugs are linked to increased suicidal thoughts and behavior among children and teens. This was the first time that the dangers of Paxil® were truly made aware to the public at large.

42. Based upon FDA review, it became apparent that the increased risk of self harm, suicidal ideation and suicidal behavior was much greater than what was represented by Defendant GSK in its own evaluation of studies.

43. On June 30, 2005, the FDA issued a public health advisory concerning suicidality in adults being treated with antidepressant medications. According to the advisory, "several recent scientific publications suggest the possibility of an increased risk for suicidal behavior in adults who are being treated with antidepressant medications."

44. In sum, Defendant GSK, in the course of conducting business in Pennsylvania, withheld the information that it gathered from clinical trials prior to October 2003, concerning the safety and efficacy of Paxil® until it was forced to disclose the information.

C. Defendant Apotex's Conduct

45. On March 31, 1998, Defendant Apotex submitted an Abbreviated New Drug Application ("ANDA") to FDA's Center for Drug Evaluation and Research ("CDER") for approval of generic paroxetine hydrochloride as safe and effective for its recommended use. In a letter to Defendant Apotex dated July 30, 2003, the FDA granted approval.

46. It is submitted, upon information and belief, that the FDA's approval of Defendant Apotex's generic paroxetine hydrochloride was based upon a review process that resulted in the FDA's findings that: (1) Defendant Apotex's generic paroxetine hydrochloride is the bioequivalent of Paxil®; (2) Defendant Apotex's generic paroxetine hydrochloride would be manufactured in a reproducible manner under controlled

conditions; (3) Defendant Apotex's manufacturing, testing, and packaging facilities were in compliance with "Good Manufacturing Practice" regulations as outlined in 21 CFR § 211.1, *et seq.*; and (4) the labeling accompanying Defendant Apotex's generic paroxetine hydrochloride was identical, in all material respects, to that accompanying Paxil®.

47. Prior to October 2003, Defendant Apotex knew or should have known of all of the information that was within the knowledge of Defendant GSK, as outlined in Paragraph Nos. 26 through 44, *supra*, when it studied, tested, designed, developed, manufactured, mixed, inspected, produced, labeled, advertised, marketed, promoted, distributed, and sold generic paroxetine hydrochloride.

48. To the extent that Defendant Apotex did not know of said information, at all times relevant to this action, Defendant Apotex studied, tested, designed, developed, manufactured, mixed, inspected, produced, labeled, advertised, marketed, promoted, distributed, and sold generic paroxetine hydrochloride in explicit and/or implicit reliance, either in whole or in part, upon Defendant GSK's representation to the general public at large, the FDA, and the medical community, including any physicians treating with and/or prescribing Paxil®, that Paxil® was safe and effective for its recommended uses, including, but not limited to, treatment of anxiety and/or depression.

49. Defendant Apotex never conducted any research, clinical trials, or any other testing for the purpose of ascertaining first-hand whether its generic paroxetine hydrochloride, which is the bioequivalent of Defendant GSK's Paxil®, was effective and/or safe for its recommended uses, including, but not limited to, treatment of anxiety and/or depression.

50. At all times relevant to this action, Defendant Apotex distributed and sold generic paroxetine hydrochloride accompanied by a warning label that was, in all material respects, identical to the warning label that accompanied Defendant GSK's Paxil®, which was inadequate to warn of the dangers and/or risks of suicide associated with Paxil® and generic paroxetine hydrochloride.

D. Decedent's Injuries

51. Plaintiff's decedent, Lois Ann Colacicco, was born on January 25, 1948.

52. Lois received her undergraduate education at Queen's College and later, in 1970, received a Masters Degree in Clinical Psychology from St. John's University.

53. On May 30, 1970, Lois married Joseph Colacicco in Queens, New York, and the couple later had two sons, Paul, who was born on March 7, 1974, and Keith, who was born on April 1, 1980.

54. From about 1997 to 2002, Lois was employed by the United Cerebral Palsy Association of Nassau County and served as the association's Director of Psychology from about 2001 to 2002.

55. From September of 2002 to September of 2003, Lois worked for the Center for the Developmentally Disabled.

56. In March 2003, Lois was diagnosed with breast cancer.

57. Thereafter, Lois underwent surgery to remove the cancer at Memorial Sloan Kettering Hospital for Cancer and Allied Diseases in New York, New York.

58. Following surgery, Lois underwent chemotherapy from July 11, 2003, to October 20, 2003.

59. On October 6, 2003, during a chemotherapy appointment with Dr. Ng, her oncologist, Lois complained of mild fatigue and depression, and Dr. Ng wrote Lois a prescription for thirty 20-milligram (mg) tablets, to be taken once daily, of either Paxil® or paroxetine hydrochloride.

60. That same day, Lois had filled and began taking a prescription of generic paroxetine hydrochloride, and thereafter, she began to manifest signs of akithisia.

61. On a return visit to Dr. Ng on October 20, 2003, Lois complained again of depression and was referred to a psychiatrist, Dr. Philip Goldberg.

62. Lois met with Dr. Goldberg on October 22, 2003, and complained of anxiety and depression. Dr. Goldberg noted that Lois was neither homicidal nor suicidal, and continued her prescription for generic paroxetine hydrochloride, 20 mg.

63. On October 28, 2003, Lois met with a social worker at a local elementary school to discuss volunteering and seemed to be in good spirits.

64. That afternoon Lois returned home. She changed into a nightgown, drew a warm bath, and submerged herself.

65. Lois then committed suicide by mutilating and slashing herself to death with a razor blade.

66. Prior to her ingestion of generic paroxetine hydrochloride, Lois had never attempted suicide and had no history of aggression towards others or herself.

67. Lois' suicide was the direct and proximate result of her ingestion of generic paroxetine hydrochloride in a manner and dosage prescribed by her treating and/or prescribing physicians.

68. Had Plaintiff's decedent known of the lack of efficacy and increased risk of suicidal ideation and behavior for some adults taking Paxil® and generic paroxetine hydrochloride she would have: been adequately informed of the adverse effects of the drug necessary to properly assess the risks and benefits of taking it; been adequately informed of the adverse effects of the drug in order to recognize the onset of said effects and discontinue using the drug; and/or not ingested the drug at all.

COUNT I – BREACH OF EXPRESS WARRANTY
(Plaintiff v. Defendant Apotex)

69. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 68 above.

70. Defendant Apotex expressly represented to users and their physicians that generic paroxetine hydrochloride was safe and fit for its intended use and purposes, that it was of merchantable quality, that it did not produce any side-effects dangerous to life, and that it was adequately tested and fit for its intended use and purposes.

71. Defendant Apotex knew or should have known that said representations and warranties were false, misleading or untrue, in that, *inter alia*, neither Paxil® nor generic paroxetine hydrochloride was safe and fit for its intended use and purposes, and, in fact, that each can cause suicidality, violence, aggression, and/or suicidal ideation to the user.

72. Plaintiff's decedent's treating and/or prescribing physicians relied upon Defendant Apotex's representations and warranties in recommending, prescribing, and/or dispensing generic paroxetine hydrochloride to Plaintiff's decedent; and Plaintiff's decedent relied upon said representations and warranties in purchasing and ingesting generic paroxetine hydrochloride.

73. As a result of the aforementioned breaches of express warranty by Defendant Apotex, Plaintiff's decedent was caused to ingest generic paroxetine hydrochloride, which caused her to commit suicide, and Defendant Apotex is liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant Apotex compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT II – BREACH OF IMPLIED WARRANTY
(Plaintiff v. Defendant Apotex)

74. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 73 above.

75. Defendant Apotex impliedly represented to users and their physicians that generic paroxetine hydrochloride was safe and fit for its intended use and purposes, that it was of merchantable quality, that it did not produce any side-effects dangerous to life, and that it was adequately tested and fit for its intended use and purposes.

76. Defendant Apotex knew or should have known that said representations and warranties were false, misleading or untrue, in that, *inter alia*, neither Paxil® nor generic paroxetine hyrdrochloride was safe and fit for its intended use and purposes, and, in fact, that each can cause suicidality, violence, aggression, and/or suicidal ideation to the user.

77. Plaintiff's decedent's treating and/or prescribing physicians relied upon Defendant Apotex's representations and warranties in recommending, prescribing, and/or dispensing generic paroxetine hydrochloride to Plaintiff's decedent; and Plaintiff's decedent relied upon said representations and warranties in purchasing and ingesting generic paroxetine hydrochloride.

78. As a result of the aforementioned breaches of implied warranty by Defendant Apotex, Plaintiff's decedent was caused to ingest generic paroxetine hydrochloride, which caused her to commit suicide, and Defendant Apotex is liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant Apotex compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT III – FRAUD BY INTENTIONAL MISREPRESENTATION AND CONCEALMENT
(Plaintiff v. Defendanst GSK and Apotex)

79. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 78 above.

80. Defendant GSK, Defendant Apotex, or both intentionally, knowingly, and recklessly misrepresented and concealed material facts concerning the risks that Paxil® and/or generic paroxetine hydrochloride posed to adults, such as Plaintiff's decedent, by, *inter alia*, failing to adequately inform the general public, the FDA, the medical community, Plaintiff's decedent's treating and/or prescribing physicians, and/or Plaintiff's decedent, that clinical trials showed that: (1) Paxil® showed no efficacy in some adults with major depressive disorder; and (2) Paxil® causes an increased risk of akathesia and suicidality in some adults.

81. Said misrepresentations and concealments by Defendant GSK, Defendant Apotex, or both were made with the intent of misleading the general public and the medical community for the purpose of more effectively advertising, marketing, and selling Paxil® and/or generic paroxetine hydrochloride.

82. Said misrepresentations and concealments by Defendant GSK, Defendant Apotex, or both were made with the intent of misleading the FDA for the purpose of obtaining the FDA's approval, and continued approval, of Paxil® and/or generic paroxetine hydrochloride.

83. Said misrepresentations and concealments by Defendant GSK, Defendant Apotex, or both were made with the intent of misleading Plaintiff's decedent's treating and/or prescribing physicians and Plaintiff's decedent; and to induce Plaintiff's decedent's treating and/or prescribing physicians to recommend, prescribe, or supply Paxil® and/or generic paroxetine hydrochloride to Plaintiff's decedent and induce Plaintiff's decedent to purchase and/or ingest Paxil® and/or generic paroxetine hydrochloride.

84. Plaintiff's decedent justifiably relied on said misrepresentations and concealments, and as a direct and proximate result of such reliance, she was caused to ingest generic paroxetine hydrochloride, the bioequivalent of Paxil®, which caused her to commit suicide, and Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT IV – NEGLIGENT MISREPRESENTATION AND NON-DISCLOSURE
(Plaintiff v. Defendants GSK and Apotex)

85. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 84 above.

86. Defendant GSK, Defendant Apotex, or both negligently misrepresented and failed to disclose material facts concerning the risks that Paxil® and/or generic

paroxetine hydrochloride posed to adults, such as Plaintiff's decedent, by, *inter alia*, failing to adequately inform the general public, the FDA, the medical community, Plaintiff's decedent's treating and/or prescribing physicians, and/or Plaintiff's decedent, that clinical trials showed that: (1) Paxil® and/or generic paroxetine hydrochloride showed no efficacy in some adults with major depressive disorder; and (2) Paxil® and/or generic paroxetine hydrochloride causes an increased risk of akathesia and suicidality in some adults.

87. Defendant GSK, Defendant Apotex, or both knew or should have known, under the circumstances, that said misrepresentations and failures to disclose were false.

88. Said misrepresentations and concealments by Defendant GSK, Defendant Apotex, or both were made with the intent to more effectively advertise, market, and sell Paxil® and/or generic paroxetine hydrochloride.

89. Said misrepresentations and concealments by Defendant GSK, Defendant Apotex, or both were made with the intent of obtaining the FDA's approval, and continued approval, of Paxil® and/or generic paroxetine hydrochloride.

90. Said misrepresentations and concealments by Defendant GSK, Defendant Apotex, or both were made with the intent to induce Plaintiff's decedent's treating and/or prescribing physicians to recommend, prescribe, or supply Paxil® and/or generic paroxetine hydrochloride to Plaintiff's decedent and induce Plaintiff's decedent to purchase and/or ingest Paxil® and/or generic paroxetine hydrochloride.

91. Plaintiff's decedent justifiably relied on said misrepresentations and concealments, and as a direct and proximate result of such reliance, she was caused to

ingest generic paroxetine hydrochloride, the bioequivalent of Paxil®, which caused her to commit suicide, and Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT V – INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS
(Plaintiff v. Defendants GSK and Apotex)

92. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 91 above.

93. Plaintiff's decedent suffered, prior to her suicide, severe emotional distress, which was the direct and proximate result of the extreme, outrageous, intentional, willful, and reckless conduct by Defendant GSK, Defendant Apotex, or both in studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertising, marketing, promoting, distributing, and/or selling Paxil® and/or generic paroxetine hydrochloride.

94. Likewise, Plaintiff suffered severe emotional distress, brought on by Plaintiff's decedent's suicide, which was the direct and proximate result of the extreme, outrageous, intentional, willful, and reckless conduct by Defendant GSK, Defendant Apotex, or both in studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertising, marketing, promoting, distributing, and/or selling Paxil® and/or generic paroxetine hydrochloride.

95. As a result of the foregoing, Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT VI – NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS
(Plaintiff v. Defendants GSK and Apotex)

96. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 95 above.

97. Plaintiff's decedent suffered, prior to her suicide, severe emotional distress, which was the direct and proximate result of the negligent conduct of Defendant GSK, Defendant Apotex, or both in studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertising, marketing, promoting, distributing, and/or selling Paxil® and/or generic paroxetine hydrochloride.

98. Likewise, Plaintiff suffered severe emotional distress, brought on by Plaintiff's decedent's suicide, which was the direct and proximate result of the negligent conduct of Defendant GSK, Defendant Apotex, or both in studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertising, marketing, promoting, distributing, and/or selling Paxil® and/or generic paroxetine hydrochloride.

99. As a result of the foregoing, Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT VII – NEGLIGENCE
(Plaintiff v. Defendants GSK and Apotex)

100. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 99 above.

101. Defendant GSK, Defendant Apotex, or both knew or should have known, by the exercise of reasonable care or the application of reasonable, developed human skill and foresight, that: (1) Paxil® and/or generic paroxetine hydrochloride showed no efficacy in some adults with major depressive disorder; and (2) Paxil® and/or generic paroxetine hydrochloride causes an increased risk of akathesia and suicidality in some adults.

102. Defendant GSK, Defendant Apotex, or both owed to Plaintiff's decedent the following duties:

(a) to exercise reasonable care in ensuring that Paxil® and/or generic paroxetine hydrochloride was not used in the treatment of adults for whom it was not effective;

(b) to exercise reasonable care in ensuring that Paxil® and/or generic paroxetine hydrochloride was not used in the treatment of adults who could be injured or harmed from the drug(s);

(c) to adequately warn Plaintiff's decedent, and her treating and/or prescribing physicians, of the risks of suicide associated with Paxil® and/or generic paroxetine hydrochloride.

103. Defendant GSK, Defendant Apotex, or both breached said duties by the manner in which they studied, tested, designed, developed, manufactured, mixed, inspected, produced, labeled, advertised, marketed, promoted, distributed, and/or sold Paxil® and/or generic paroxetine hydrochloride.

104. As a direct and proximate result of the aforesaid breaches, Plaintiff's decedent was caused to ingest generic paroxetine hydrochloride, which resulted in her

committing suicide, and Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT VIII – NEGLIGENCE *PER SE*
(Plaintiff v. Defendants GSK and Apotex)

105. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 104 above.

106. Defendant GSK, Defendant Apotex, or both owed a duty to Plaintiff's decedent to adequately warn her, and her treating and/or prescribing physicians, of the risks of suicide associated with Paxil® and/or generic paroxetine hydrochloride.

107. Defendant GSK breached said duty by failing to comply with federal regulations concerning the study, testing, design, development, manufacture, mixing, inspection, production, labeling, advertisement, marketing, promotion, distribution, and/or sale of prescription drugs, including but not limited to, 21 CFR §§ 201.57 and 314.70.

108. Defendant Apotex breached said duty by failing to comply with federal regulations concerning the study, testing, design, development, manufacture, mixing, inspection, production, labeling, advertisement, marketing, promotion, distribution, and/or sale of generic prescription drugs, including but not limited to, 21 C.F.R. §§ 201.57 and 314.70.

109. As a direct and proximate result of the aforesaid breaches, Plaintiff's decedent was caused to ingest generic paroxetine hydrochloride, which resulted in her

committing suicide, and Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT IX – STRICT PRODUCTS LIABILITY
(Plaintiff v. Defendants GSK and Apotex)

110. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 109 above.

111. Defendant GSK's Paxil® was unreasonably dangerous, and Defendant GSK is strictly liable to Plaintiff and Plaintiff's decedent, as a result of the following conduct by Defendant GSK:

a) studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertising, marketing, promoting, distributing, and/or selling Paxil® in a defective manner;

b) failing to supply adequate warnings with Paxil®.

112. Defendant Apotex's generic paroxetine hydrochloride was unreasonably dangerous, and Defendant Apotex is strictly liable to Plaintiff and Plaintiff's decedent, as a result of the following conduct by Defendant Apotex:

a) studying, testing, designing, developing, manufacturing, mixing, inspecting, producing, labeling, advertising, marketing, promoting, distributing, and/or selling generic paroxetine hydrochloride in a defective manner;

b) failing to supply adequate warnings with generic paroxetine hydrochloride.

113. As a direct and proximate result of the foregoing conduct by Defendant GSK, Defendant Apotex, or both, Plaintiff's decedent was caused to ingest generic paroxetine hydrochloride, which resulted in her committing suicide, and Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT X – VIOLATION OF CONSUMER PROTECTION LAW
(Plaintiff v. Defendants GSK and Apotex)

114. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 113 above.

115. Defendant GSK, Defendant Apotex, or both violated 73 P.S. § 201-2(4)(v) by representing that Paxil® and/or generic paroxetine hydrochloride possessed uses and/or benefits that each did not possess; and 73 P.S. § 201-2(4)(xxi) by engaging in fraudulent conduct which created the likelihood of confusion or misunderstanding with respect to Paxil® and/or generic paroxetine hydrochloride.

116. In the alternative, the conduct of Defendant GSK, Defendant Apotex, or both violated N.Y. Gen. Bus. Law § 349, *et seq.*, which makes unlawful "deceptive acts or practices in the conduct of any business, trade, or commerce or in the furnishing of any service."

117. As a result of said violations, Plaintiff was caused to ingest generic paroxetine hydrochloride, which resulted in her committing suicide and caused Plaintiff and/or Plaintiff's decedent to suffer an ascertainable loss of money. Defendant GSK, Defendant Apotex, or both are liable to Plaintiff.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT XI – SURVIVAL ACTION
(Plaintiff v. Defendants GSK and Apotex)

118. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 117 above.

119. Plaintiff, as Executor of the Estate of his decedent, Lois Ann Colacicco, brings this action on behalf of the Estate of Lois Ann Colacicco under and by virtue of 20 Pa.C.S.A. § 3373, or, in the alternative, under and by virtue of N.Y. EPT Law § 11-3.1.

120. As a direct and proximate result of the acts and/or omissions of Defendant GSK, Defendant Apotex, or both, as listed in this Complaint, Plaintiff's decedent suffered and Defendant GSK, Defendant Apotex, or both are liable for, the following:

a) Plaintiff's decedent's pain and suffering;

b) Plaintiff's decedent's loss of earning and right to earn a living; and

c) other financial losses to Plaintiff's decedent as a result of her death.

121. As a result of the foregoing, the Estate of Lois Ann Colacicco, is entitled to recover compensatory and punitive damages for Plaintiff's decedent's pain and suffering, as well as an amount equal to the gross amount that Plaintiff's decedent would have earned during her life expectancy, subject to any provisions she would have made for her surviving family members, which are recoverable under Count XII, *infra*, and subject to her cost of maintenance.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT XII – WRONGFUL DEATH
(Plaintiff v. Defendants GSK and Apotex)

122. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 121 above.

123. Plaintiff, as Executor of the Estate of his decedent, Lois Ann Colacicco, brings this action on behalf of himself and others as beneficiaries of the Estate of Lois Ann Colacicco under and by virtue of 42 Pa.C.S.A. §8301, *et seq.*, or, in the alternative, under and by virtue of N.Y. EPT Law § 5-4.1.

124. Each of the various wrongful acts, negligence, and/or omissions of Defendant GSK, Defendant Apotex, or both, as listed in this Complaint, were the direct and proximate cause of Plaintiff's decedent's wrongful death.

125. As a direct and proximate result of Plaintiff's decedent's wrongful death, she has been prevented from performing all of her usual duties, occupations, recreational activities and avocation, all to her and her beneficiaries' loss and detriment.

126. As a direct and proximate result of Plaintiff's decedent's wrongful death, her beneficiaries have suffered, will continue to suffer for an indefinite period of time in the future, and are entitled to recover for, the following:

(a) a loss of financial support;

(b) funeral expenses and any expenses of administration;

(c) a loss of love, affection, consortium, and services;

(d) any other damages recoverable under 42 Pa.C.S. § 8301, *et seq.* or any other applicable law.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

COUNT XIII - PUNITIVE DAMAGES
(Plaintiff v. Defendants GSK and Apotex)

127. Plaintiff incorporates by reference, as if fully set forth herein, the allegations in Paragraph Nos. 1 through 126 above.

128. The acts and/or omissions of Defendant GSK, Defendant Apotex, or both were intentional, wanton, willful, and outrageous, and said acts and/or omissions were committed with gross negligence, reckless disregard of, and deliberate, callous and reckless indifference to the rights, interests, welfare and safety of Plaintiff's decedent.

129. As a direct and proximate result of said conduct, Plaintiff's decedent was caused to ingest generic paroxetine hydrochloride, which resulted in her committing suicide.

130. As a result of the foregoing, Plaintiff is entitled to an amount of punitive damages required by justice.

WHEREFORE, Plaintiff claims of Defendant GSK, Defendant Apotex, or both compensatory damages, punitive damages, interest and allowable costs of suit.

BY: _____

Harris L. Pogust, Esquire
Derek Braslow, Esquire
CUNEO, POGUST & MASON, LLP
Eight Tower Bridge
161 Washington Street, Suite 1520
Conshohocken, PA 19428

Dated: October 19, 2005

JURY TRIAL DEMANDED

Please take notice that the Plaintiff demands a trial by jury as to all issues in the above matter.

BY: 

Harris L. Pogust, Esquire
Derek Braslow, Esquire
CUNEO, POGUST & MASON, LLP
Eight Tower Bridge
161 Washington Street, Suite 1520
Conshohocken, PA 19428

Dated: October 19, 2005